EXHIBIT H

September 10, 2003 Vol. XXV Issue 36 036-3 NEW45 79-58567

DEPARTMENT OF STATE Division of Administrative Rules

NEW YORK STATE TO THE POLICE OF THE POLICE O

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State agencies must specify in each notice the last date on which they will accept public comment. Agencies always accept public comment for a minimum of 45 days following publication in the *Register* of a Notice of Proposed Rule Making, and for 30 days after publication of a Notice of Revised Rule Making. When a public hearing is required by statute, the hearing cannot be held until 45 days after publication of the notice; and comment must be accepted for at least five days after the last required hearing. When the public comment period ends on a Saturday, Sunday or legal holiday, agencies accept comment through close of business on the next succeeding workday.

For notices published in this issue:

- the 45-day period expires on Saturday, October 25, 2003
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counseling session. The Department believes that most infants identified with CF will be found to have at least one mutation associated with CF; carriers of CF mutations will be able to pass the gene on to their children. Therefore, in addition to confirmatory testing and genetic counseling of families with affected infants, carriers' families should be offered genetic counseling at a cost of \$150 per session, to determine the risk of conceiving children with CF in the future.

The Department expects that costs of medical services and supplies will be reimbursed by all payor mechanisms now covering the care of children identified with conditions already in the newborn screening panel, as well as children diagnosed with CF, CAH or MCADD, by means of targeted testing at the primary care level. Payors include indemnity health plans, managed care organizations, and New York State's medical assistance program (Medicaid), Child Health Plus and Children with Special Health Care Needs programs. The Department also expects that medical eare providers will claim reimbursement from one or more of these payors at a rate equal to the usual and customary charge, thereby recouping costs.

Overall health care costs for definitive diagnosis and comprehensive medical management of affected individuals will vary significantly, primarily by the condition and the services and supplies required for sustaining some level of continued health. Many of the costs associated with medical management of a child affected with CF, and to lesser extent CAH and MCADD, are not attributable solely to the proposed regulation, as most would have been incurred at some point following diagnosis by targeted testing at the primary care level. Although the proposed rule's advancement of early diagnosis may result in increased overall lifetime costs for patients who would have died in the absence of screening, e.g., those with MCADD, substantial cost-savings are likely to be accrued from prevented medical complications, to be set off against treatment costs. Early diagnosis and early treatment may prevent or lessen irreversible organ damage, and thereby reduce costs related to caring for affected individuals incurred by New York's health care and education system infrastructure. Morcover, early detection affords affected individuals with the opportunity for improved quality of life, a benefit that cannot be quantified.

Economic and Technological Feasibility:

The proposed regulation would present no economic or technological difficulties to facilities located in rural areas.

Minimizing Adverse Impact:

The Department did not consider less stringent compliance requirements or regulatory exceptions for facilities located in rural areas because of the importance of the added infant testing to statewide public health and welfare. These amendments will not have an adverse impact on the ability of regulated parties in rural areas to comply with Department requirements for mandatory newborn screening, as full compliance would entail minimal enhancements to present collection, reporting, follow-up and record-keeping practices.

Participation by Parties in Rural Areas:

On October 16, 2000, the Commissioner of Health sent a letter to all New York State-licensed physicians informing them of the Department's intent to add testing for CF, CAH and MCADD to the State's newborn screening panel. The Newborn Screening Program distributed the Commissioner's letter to local health departments, and all rural facilities engaged in newborn screening, specifically, hospital chief executive officers and their designees; directors of pediatric units; and pediatricians and licensed midwives identified by the program as involved in newborn screening. The Department received few comments from these mailings, the vast majority of which only posed specific questions about the initiative, to which written responses were provided. No adverse comments were submitted by the medical community.

Based on Department outreach efforts, strong support for the amendment is expected from patient advocacy organizations representing affected individuals, as well as the medical community at large. The Department is not aware of any opposition to expanded newborn testing, or of any prospect of organized opposition from providers located or operating in rural areas. It is believed that the health care system has been effectively primed for integrated care of identified infants. Consequently, regulated parties should be able to comply with these regulations as of their effective date, effective upon publication of the Notice of Adoption in the New York State Register.

Job Impact Statement

A Job Impact Statement is not required because it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs and employment opportunities. The amendment proposes the addition of three disorders—cystic fibrosis (CF), congenital adrenal hyperplasia (CAH) and medium-chain acyl-CoA dehydrogenase

deficiency (MCADD)—to the scope of newborn screening services already provided by the Department. It is expected that, of the small number of regulated parties that will experience moderate rather than minimal impact on their workload, few, if any, will need to hire new personnel. Therefore, this proposed amendment carries no adverse implications for job opportunities.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Public Water Systems-MTBE

I.D. No. HLT-36-03-00009-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule: Proposed action: Amendment of Subpart 5-1 of Title 10 NYGRE Statutory authority: Public Health Law, sections 201(1) and 225(1) Subject: Public water systems-MTBE.

Purpose: To adopt a revised maximum containment level (MCL) of 0.010 mg/L for methyl-tertiary-butyl-ether (MTBE) and prescribe analytical procedures and monitoring requirements for affected public water systems.

Substance of proposed rule: Section 5-1.52, Table 3 is amended to add the following contaminant and to establish a more restrictive maximum contaminant level (MCL) of 0.10 MCL (mg/L for Methyl-tertlary-butyl-ether (MTBE).

Section 5-1,52, Table 9B is amended to add methyl-tertiary-butyl-ether (MTBE) as a contaminant for which monitoring would coincide with pre-existing principal organic contaminant monitoring requirements for community and nontransient noncommunity water systems.

Section 5-1.52, Table 13 is amended to extend the provisions for state, consumer or public notification to MTBE as required by this action.

Appendix 5-C, II. ORGANIC CHEMICALS, is amended to include a Section C. - Methyl-tertiary-butyl-ether (MTBE) Analytical Requirements. This section includes approved analytical methods, namely, EPA Method 502.2 (as most recently amended by the State) and EPA Method 524.2

Section 5-1.22(b) is amended to reference the 1997 edition of the "Recommended Standards for Water Works" as this document is updated every five years, and currently, the 1987 edition is referenced. Section 5-1.22(b) is amended to also reference the 1995 edition of the Department's "Rural Water Supply" booklet, as the 1966 edition is currently referenced. The most current versions of these documents are already in widespread use

Appendices 5-A and 5-B are amended to reflect the 1997 edition of the "Recommended Standards for Water Works" and the 1995 edition of "Rural Water Supply".

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this enotice.

Summary of Regulatory Impact Statement

Statutory Authority

The statutory authority for the proposed revisions can be found in Public Health Law, Sections 201 and 225. Section 201 of the Public Health Law establishes the powers of the Department of Health to supervise and regulate the sanitary aspects of public water systems. Section 225 of the Public Health Law provides that the State Sanitary Code may deal with any matters affecting the security of life or health or the preservation and improvement of public health in the State and establishes the powers of the Public Health Council to establish, amend or repeal regulations of the State Sanitary Code.

Legislative Objective

The changes to the State Sanitary Code are being proposed pursuant to the legislative objective set forth in the Public Health Law Section 225 which authorizes the Public Health Council to amend the State Sanitary Code to insure the protection of public health. Since there is currently aspecific maximum contaminant level (MCL) for Methyl-tertiary-butylether (MTBE) which pertains to public water systems, the New York State Department of Health's (Department's) unspecified organic contaminant

(UOC) standard of 0.05 mg/L applies. The following changes establish a more restrictive MCL for MTBE in drinking water and adopt monitoring requirements for this chemical.

Section 5-1.52, table 3 has been amended to establish an MCL of 0.010 mg/L for MTBE because many surveys, including those conducted by the Department and the US Geological Survey, have shown detections of MTBE in groundwater. MTBE has been detected in some public water systems.

Section 5-1.52, table 9B has been modified to include (MTBE) as a contaminant for which monitoring would coincide with pre-existing principal organic contaminant monitoring requirements for community and nontransient noncommunity water systems.

By including MTBE under the routine monitoring requirements for public water systems, exposure to this chemical can be assessed and appropriate action taken to reduce unnecessary risk to the consumer.

Section 5-1.52, table 13 extends the provisions for state, consumer or public notification to MTBE.

Section 5-1.22(b) has been modified to ensure that the 1997 version of the "Recommended Standards for Water Works" and the 1995 version of the Department's "Rural Water Supply" booklet (Appendices 5-A and 5-B) are referenced. The most current versions of these documents are already in widespread use.

Appendix 5-C has been modified to include a new Section II, subsection c dealing with MTBE analytical requirements.

Needs and Benefits

The need for this amendment has been brought to light by the many surveys, including those conducted by the Department and the US Geological Survey, which have detected MTBE in ground water. There is sufficient toxicological data to raise concern over the potential human health risks of MTBE in drinking water. Numerous reports have focused national attention and public policy discussions on the MTBE issue, which has lead to legislative and public pressure for MTBE regulations.

The toxicological data on the known and potential health effects of MTBE in humans and animals support concerns about the potential health risks from MTBE in drinking water. There are no data on the human noncancer or cancer effects of short-term or long-term exposure to MTBE in drinking water. Most of the information on the potential risks of exposures comes from laboratory studies of animals exposed by inhalation or by the injection of MTBE in oil directly into the stomach (gavage dosing). Although these studies identify the central nervous system, kidneys, liver, gastrointestinal tract, and blood as sensitive to the noncancer effects of MTBE, additional studies are needed to fully characterize the noncancer health effects of MTBE. In addition, MTBE is an animal carcinogen. In long-term studies, MTBE induced lymphomas in female rats, testicular and kidney tumors in male rats, and liver tumors in male and female mice. The way MTBE causes these cancers is unknown; thus, these animal data support concerns about the carcinogenic potential of MTBE in humans.

The use of the additive has unequivocally lead to ground water contamination, primarily because gasoline spills/leaks are unavoidable and MTBE tends to move quickly and over great distances in ground water. Concerns about ground water contamination lead to a United States Environmental Protection Agency (USEPA) "Blue Ribbon Panel" to call for a phase-out of MTBE in gasoline with the caveat that the reductions in air pollution achieved with the use of MTBE are not lost. As a result, EPA has proposed action to phase out MTBE.

An extensive sampling program of public and private water supplies in Northeastern United States (See reference (1)) detected low levels of MTBE in about 15% of the samples. Another sampling program of private water supplies in New York State (See reference (2)) detected MTBE concentrations at or above the detection limit (1 mcg/L) in 28% of the samples. Additionally, the New York State Department of Environmental Conservation (NYSDEC), through its Spill Response Program, has documented that 867 private wells and 47 public water supply wells have observed MTBE impacts (based on 1998 data). As part of the NYSDOH's ongoing water quality surveillance program, MTBE analysis has been done on over 1400 samples, representing 1248 public water supply systems, over the past 5 years. One sample result exceeded the state drinking water maximum contaminant level of 50 mcg/L.

Although the MCL applies to public water systems, it will be used as a basis for spill cleanup where private wells are contaminated. It is estimated that between 0.6 and 3.0 percent of private wells will be impacted by MTBE at levels exceeding 10 mcg/L (See reference (1)). It is estimated that approximately 4,000 — 23,000 private wells will be affected by the proposed standard of 10 mcg/L. Once the proposed standard is adopted, it is anticipated that only 20 percent of the estimated number of wells

exceeding the proposed standard will be discovered, remediated and exposures reduced. This results in a range of 800 4,400 private wells with reduced MTBE exposures.

Costs

The amended regulations have no cost impacts that affect all regulated parties. Monitoring for MTBE will be included with the routine compliance monitoring for volatile organic compounds (VOCs). Therefore, there will be no additional cost for MTBE routine monitoring as analysis for this compound can be included using existing methods for the analysis of VOCs.

As discussed in the Needs and Benefits section, this rule does not apply to private wells. However, the proposed standard will be used as guidance by the New York State Department of Environmental Conservation (NYS-DEC) for remediation of private wells contaminated by gasoline products, thereby providing protection for private wells. The largest cost impact will come from providing treatment for the estimated 800 4,400 private wells. It is estimated that treatment for a private well will cost \$10,000, including installation and 5 years of operation and maintenance of a granular activated carbon treatment system. This average estimate per household corresponds to an estimated total cost impact of \$8,000,000 to \$44,000,000 for New York State to treat private wells for MTBE contamination at the proposed MCL. Some of these funds necessary to cover treatment of private wells, may come from the NYSDEC Spill Fund when the responsible party can not be assessed.

Cost to State Government

The cost to State government will affect those state agencies that operate water systems as defined in Part 5 of the State Sanitary Code. There are approximately 25 state owned or operated facilities. Currently, there are no known state owned and operated public water systems affected by MTBE contamination.

The annualized State government cost for MTBE monitoring will be negligible since monitoring for MTBE will be included with the routine compliance monitoring for (VOCs). An exceedance of the MCL would require additional monitoring costs as described in the "Monitoring Costs" section.

The largest cost incurred by State government will be for treatment of private wells for MTBE contamination at the proposed MCL. This cost corresponds to an estimated impact of \$8,000,000 to \$44,000,000. Some of these funds necessary to cover treatment of private wells, may come from the NYSDEC Spill Fund when the responsible party can not be assessed.

Cost to Local Government

The amended regulations apply to all local governments (town, village, county, authorities or area wide improvement districts) which own and/or operate a water system having its own source of water and are considered community water systems. There are approximately 1,000 water systems that are owned or operated by local government. If required treatment costs are proportional to these systems, the total capital cost and the annual operation and maintenance cost is projected to range from \$3,000,000 to \$8,000,000.

Cost to Private Regulated Parties

The cost incurred by a privately owned water system that meets the definition of a public water system is not different than a system operated by local government. Included in this group of an estimated 2,350 water systems are: 1) privately owned community water systems consisting of private water systems serving residential suburban areas (realty subdivisions), mobile home parks and apartment buildings, residential health care facilities, private schools/colleges, and residential private institutions; and 2) privately owned and operated nontransient noncommunity water systems consisting mainly of industrial, commercial and private buildings, nursery schools, day care centers and nonresidential health care facilities. Also, nearly all of the 6,481 transient noncommunity water systems, such as restaurants, motels and campsites are privately owned. Thus, there are approximately 8,831 of these privately held water systems.

There will be no annualized cost to most of these systems for MTBE monitoring since monitoring for MTBE will be included with the routine compliance monitoring for (VOCs). Treatment costs associated with known spills may be covered by the Spill Fund, or through the pursuit of responsible parties.

Cost to State and Local Health Departments

The cost to the State Health Department initially will be approximately 2 man-years during the preparation and implementation phase of these regulations. However, once the amendment is implemented, it is estimated to be less than 0.5 person-years per year for these activities in addition to oversight and training. Since monitoring for MTBE will be included with

the routine compliance monitoring for VOCs, the time necessary for implementation should be no more than 0.1 person-years per year.

Local Government Mandates

The requirements contained in this State proposed rule apply to any water-system impacted by MTBE contamination and which has its own source(s) of water and is owned and/or operated by a county, city, town, village or school district. Fire districts are not included in the regulatory definition of a water system to which this proposed rule applies.

Paperwork

There will be no significant increase in paperwork for local and State health departments resulting from this rule. MTBE monitoring will be included under the routine compliance monitoring requirements for public water systems. As such, MTBE monitoring results will be tracked and reported simultaneously with existing routine compliance monitoring re-

Duplication

There will be no duplication of existing State or Federal regulations. The USEPA will not likely have an MCL for MTBE until 2008 and the MCL may be higher than 10 mcg/L.

Alternatives

One alternative is to keep the existing MCL of 50 parts per billion. Another alternative is waiting for the federal MCL in 2008, or a secondary federal MCL (typically a less stringent MCL established for aesthetic reasons, such as taste and order) which is anticipated to be established sometime in 2001. The Department chose to propose it s own MCL now, to reduce exposure to a potentially harmful level of MTBE.

Federal Standards

This rule will not exceed any minimum standards of the federal government as there is no federal MCL for MTBE to date.

Compliance Schedule

Compliance with this amendment would be required upon promulgation. The proposed rule will affect only a small number of public water systems and the treatment technology needed for compliance is readily available and unsophisticated.

References

(1) New Hampshire Department of Environmental Services. "Assessment of the Proposed Revision to the Drinking Water and Groundwater Standards for Methyl Tertiary Butyl Ether (MTBE)". January 20, 2000.

New Hampshire's Department of Environmental Services in consultation with the New Hampshire Department of Health and Human Services. Bureau of Health Risk Assessment, reviewed the current primary and secondary drinking water standards and ambient groundwater quality standards for the gasoline additive MTBE. During the review process, private well data was evaluated to determine the potential cost of treatment to remove MTBE from individual private wells in the state of Maine. This data was extrapolated for similar cost estimates in New York State for this rule proposal. For more information on this study, or to obtain a copy of this document, contact Kim Evans at the NYS Department of Health, Flanigan Square, 547 River Street, Troy, NY, or call at 518/402-7713.

(2) Lince, D. and Kaplan, J. "Health Consultation for Methyl-tert-Butyl-Ether in Private Wells near Gasoline Stations in New York" (prepared under a cooperative agreement between New York State Department of Health and the Agency for Toxic Substance and Disease Registry); July 26, 1999 public comment draft.

This study investigated whether widespread MTBE contamination is occurring in private wells near gasoline stations in NYS, compared to those further away form gasoline stations. In addition, this study investigated whether the levels of contamination differ significantly between regions of reformulated gasoline use and regions of conventional gasoline use. The results of this study were used to estimate potential private well contamination from MTBE for the purpose of this proposal. For more information on this study, or to obtain a copy of this document, contact Kim Evans at the NYS Department of Health, Flanigan Square, 547 River Street, Troy, NY, or call at 518/402-7713.

Regulatory Flexibility Analysis

Effect on Small Business and Local Governments

Nearly all of the public water systems affected by this amendment are owned or operated by either a small business or local government. There are approximately 2,477 small (serving less than 3,300 people) privately owned community and nontransient noncommunity water systems in New York State which are affected by this amendment. Nearly all of these systems are believed to meet the definition of a small business. The small community systems consist mostly of suburban water systems serving realty subdivisions and long established water companies serving all or part of a local municipality such as a village. There are 356 systems in this category the remaining 2,121 water systems primarily consist of mobile home parks, apartment complexes and condominiums.

There are approximately 1,000 water systems owned and/or operated by local government. These include those serving municipalities (town, village, city, authority or area wide improvement district), schools or government buildings.

Compliance Requirements

The amendment establishes a maximum contaminant level (MCL) for methyl-tertiary-butyl-ether (MTBE) of 0.010 mg/L. Monitoring will be required of all community and nontransient noncommunity water systems. MTBE monitoring will be included with the routine compliance monitoring for volatile organic compounds (VOCs). As with current compliance requirements, the absence of detectable amounts of the contaminant will generally result in a decrease in sample frequency and increase if detected. These monitoring results must be summarized and reported to the state.

Failure to comply with the MCL results in a requirement for public notification which must include mandatory health effects language.

Note: The MCL of 0.010 milligrams per liter (mg/L) for MTBE is equivalent to 10 micrograms per liter (mcg/L). For ease in reference, the MCL of 10 mcg/L will be used throughout the remainder of this document.

Professional Services

Public water systems impacted by this amendment will require the professional services of a certified or approved laboratory to perform the analyses for MTBE. The laboratory used must be one approved by the Department under its Environmental Laboratory Approval Program (ELAP). It is estimated that sufficient laboratory capability and capacity is available.

A licensed professional engineer is required to design treatment facilities to meet the MCL or design facilities for accessing an alternate source.

Compliance Costs

The amended regulations may have cost impacts that affect community and nontransient noncommunity public water systems that serve 25 or more persons or have 15 or more service connections, since state discretion still applies to compliance monitoring. The amended regulations require monitoring for an additional contaminant, namely MTBE. Monitoring for MTBE will be included with the routine compliance monitoring for volatile organic compounds (VOCs). Therefore, there will be no additional cost for MTBE routine monitoring as analysis for this compound can be included using existing methods for the analysis of VOCs. Monitoring for VOCs applies to points of entry of water from all combined or separate sources of water and before water treatment, if present.

Based upon available data and past limited water quality surveys of water systems nationally and those performed by the Department, the detection of MTBE is expected to occur in approximately five percent of public water systems. This corresponds to approximately 174 small businesses and local governments having MTBE detections. Sampling of public water systems conducted to date, shows that only 17 will violate the proposed MCL of 10 mcg/L for MTBE. Consequently, these systems will have to install treatment facilities.

If a MCL is exceeded and water treatment is the only option available, the cost projected by 1996 USEPA data will vary with system size as summarized in the table below.

Conteminant	Public Weter System Meximum Water Usage (Callons Per Day)	Estimated Capital Cost (Dollars Per Gallon) ¹	Total Capital Con (Dollars) ³	Estimated Annual Operation and Maintenance Cost (Dollars) ³	Estimated Number of Systems ⁴
мтве	<000,01>	1.50+	10,000 - 15,000	1,500 - 3,000+	57(1)
MTBB	10,000 - 30,000	1.50 - 1.00	15,000 - 30,000	3,000 4,000+	14(6)
мтви	30,000 - 50,000	1.00 - 0.90	30,000 41,000	4,000 - 5,000+	g(4)
MTBE	50,000 - 100,000	0.90 - 0.70	45,000 - 70,000	5,000 - 6,000+	4(6)
MTBE	100,000 - 500,000	0.70 - 0.44	70,000 - 220,000	6,000 - 9,125	-17
MTBE	\$00,000 - 1,000,000	0.44 - 0.40	220,000 - 400,000	9,125 - 18,250	- 0

- Cost it based on the maximum delty flow of 200 gallons per person per day or from available water consumption de 3 Size variations may effect costs. Urben areas and rise conditions may increase capital costs of snantcelly.

 Annual Operation and Maintenance Cost is based on \$0.05 per 1,000 gallons of water treated for larger systems, tree least 100,000 gpd, Por systems treating test them 100,000 gpd, costs were exceptled eating private well remediate (RYSDEC).
- (NYSDEC).

 The number of systems is based on local bealth unit and swallable New York State MTBE electronic data.
 In addition to the number of systems known to be treated for MTBE, the estimated number of systems that will require
 MTBE treatment in the future is based on a one proceed projection of all transfers inconcommunity systems, the is
 consistent with studies the have been published nation/vide.

 Approximately half of all commentity and nontransient soncommunity systems have been sampled for MTBE to date,
 therefore the estimated number of systems requiring treatment has been doubted to account for known contaminated wells,
 and discovery of potential future contemination events.

 The projection for larger systems is still unknown, but may be as high as 6 systems based on 3 known, large systems
 affected by MTBE contamination, and discovery of potential future consumination events.

The exact cost for monitoring and treatment of MTBE for the approximately 174 potentially affected public water systems owned or operated by either a small business or local government cannot be determined since larger systems are likely to have more entry points and higher water usage while small systems usually have a single entry point and lower water

usage. Furthermore, monitoring is likely to vary depending on the water system and MTBE concentrations and the necessity for installing treatment facilities or an alternate source can not be predicted. It is estimated that a public water system that exceeds the MCL for MTBE, will have to conduct quarterly or more frequent monitoring for MTBE per affected entry point. The cost for analysis of MTBE is approximately \$140 per analysis. Therefore, the minimum additional cost for MTBE analysis is \$560 per year. Treatment cost is dependent upon system size and number of affected entry points and can be determined by the costs outlined in the table above.

Economic and Technological Feasibility

Economically, compliance with this amendment will not increase monitoring costs because monitoring will be included with the routine compliance monitoring for VOCs. Additional costs would be associated with an exceedance of the MCL that would require installation of treatment facilities, as discussed in the preceding section. Capital costs are estimated to be no more than \$15,000 and the operating costs not more than \$3,000 per year. These costs are proportionate to typical operating costs.

With regard to technology, analytical methods exist for accurate MTBE monitoring results and these are included as part of this amendment. The monitoring results will provide the basis for water system compliance with the amendment. Furthermore, there are technologically feasible alternatives available for MTBE treatment. The Department has the staff and the expertise to provide any necessary technical guidance.

Minimizing Adverse Impact

The adverse impact of this amendment is minimized since monitoring for MTBE will be included with the routine compliance monitoring for VOCs. Therefore, there will be no additional monitoring costs. The inclusion of MTBE will not modify the current monitoring criteria for a public water system. The MCL is a performance standard.

Small Business and Local Government Participation

While the Department has not actively conducted a Public Outreach Program, the proposed rule is indeed a response to increased public awareness and concern about the widespread use and increased number of detections of MTBE in drinking water supplies nationally. This increased level of concern is evidenced by the several events that have recently taken place locally and nationally in an effort to gain a better understanding of the public health concerns surrounding the use of MTBE.

In November 1998, the EPA created a blue-ribbon panel of leading experts from the public health and science communities, automotive fuels industry, water utilities (many of which are small businesses), and local and state government to focus on the issues posed by the use of MTBE and other oxygenates in gasoline. The Blue Ribbon Panel findings included recommendations to enhance, accelerate, and expand existing programs to improve protection of drinking water supplies from contamination. The recommendations focused on prevention, treatment and remediation, as well as reducing the use of MTBE.

In 1998 the NYS Legislative Commission on Water Resource Needs of NYS and Long Island began holding hearings on water quality and quantity issues throughout NYS. As a result of those hearings, Suffolk and Nassau County Health Departments began requiring all water suppliers to sample for MTBE as part of their normal sampling program for organic

The State of New York provided a press release stating that the Department of Health would be initiating rule making to develop a stricter standard for MTBE. The general public was given an opportunity to respond to the press release.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas

This regulation would apply to rural areas of the state, potentially impacting approximately 7,800 small public water systems located throughout rural areas as defined by New York State.

Some of these systems may be located near or within metropolitan areas. For these systems, there is often a greater opportunity to connect to a municipal water supply system. This type of regionalization is a less costly compliance alternative available to systems which are adjacent to metropolitan areas. Por the majority of systems, which are truly rural, this option does not exist. However, there is less methyl-tertiary-butyl-ether (MTBE) impact in rural areas, which comprise most of upstate New York. Gasoline stations in the upstate or northern region are supplied with conventional gasoline. Conventional gasoline may also contain MTBE, but at relatively low concentrations ranging from 1% to 5% by volume and then usually only in premium grade gasolines, which constitute a relatively small percentage of gasoline sold. In contrast, gasoline stations in the southern region (where rural areas are less predominant) are supplied with reformulated gasoline (RFG), which contains fuel oxygenates, (such as MTBE) in

all grades. When MTBE is used as the fuel oxygenate, as it is in 84% of all RFG sold, MTBE concentrations range from 11-15% by volume (Lince et. al. 1999). In addition, due to the nature of rural areas, water supplies are less likely to be near a leaky gasoline tank. Therefore, public and private water supplies in rural areas are less likely to be impacted by MTBE contamination.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services

Demonstrating compliance with the new maximum contaminant level (MCL) for MTBE being imposed by this regulation will add to existing record keeping requirements for impacted systems. These requirements include reporting of results, recordkeeping, reporting violations of the established MCL and other compliance requirements which cover compounds currently regulated in drinking water.

Small public water supply systems will require the professional services of a certified or approved laboratory to perform the water analyses for MTBE. The laboratory used must be one approved by the New York State Department of Health (Department) under its Environmental Laboratory Approval Program (ELAP). It is estimated that sufficient laboratory capability and capacity is available. Public notice is required when a system violates these regulations.

A licensed professional engineer is required to design treatment facilities to meet the MCL or design facilities for accessing an alternate source.

Costs

The amended regulations have cost impacts that affect all regulated parties. The amended regulations require monitoring for an additional contaminant, namely MTBE. Monitoring for MTBE will be included with the routine compliance monitoring for volatile organic compounds (VOCs). Therefore, there will be no additional cost for MTBE routine monitoring as analysis for this compound can be included using existing methods for the analysis of VOCs. Monitoring for VOCs applies to points of entry of water from all combined or separate sources of water and before water treatment, if present.

Based upon available data and past limited water quality surveys of water systems nationally and those performed by the Department, the detection of MTBE is expected to occur in approximately 5 percent of small public water systems. This corresponds to approximately 390 small water systems located in rural areas having MTBE detections. Sampling of all public water systems conducted to date, shows that only 17 (3 of which are in areas considered rural) will violate the proposed MCL of 10 mcg/L for MTBE. Consequently, these systems will have to install treatment

If a MCL is exceeded and water treatment is the only option available, the cost projected by 1996 United States Environmental Protection Agency (USEPA) data will vary with system size as summarized in the table below.

Contermentant	Public Water System Maximum Water Usage (Gations Per Day)	Estimated Capital Cost (Dollars Per Gallon) ²	Tatal Capital Cost (Dollars) ³	Estimated Annual Operation and Maintenance Cost (Dollars) ³	Estimated Number of Systems ²
MTBE	<10,000	1.50 +	10,000 ~ 15,000	1,300 - 3,000+	57(5)
MTBE	10,000 - 30,000	1.50 - 1.00	15,000 - 30,000	3,000 - 4,000+	144
MTBE	30,000 - 50,000	1.00 ~ 0.90	10,000 ~ 45,000	4,000 - 5,000+	B(4)
MTBE	50,000 - 100,000	0.90 - 0.70	45,000 70,000	5,000 6,000+	4/6)
MTBE	100,000 - 500,000	0.70 - 0 44	70,000 - 220,000	6,000 - 9,175	-0
MTBE	500,000 1,000,000	0.44 0.40	220.000 - 400.000	9.125 - 18.250	

- Cost is based on the maximum daily flow of 200 gallons per person per day or from available water consumption data.

 Size variations may affect costs. Urban areas and rite conditions may forcease capital costs demonstrating of Annial Operation and Maintenance Cost is based on 50.05 per 1,000 gallons of water transict for integer systems, treating to least 100,000 gpd. For systems usualing less than 100,000 gpd, costs were extrapolated using private well remediation cost
- (FYSDEC)

 The number of systems is been on local health unit input and available. New York State MTBB electronic data.

 In addition to the number of systems known to be treated for MTBB, the estimated number of systems that will require MTBB treatment in the future it based on a one percent projection of all tractical noncommunity systems, that is consistent with studes that have been published nationally of all constitutions are stated in the programment of all tractical noncommunity systems, that is consistent when the set of all constrained and interesting the setting and constrained for the programment of a systems requiring treatment has been doubled to account for known contamination events.

 The projection for larger systems is still unknown, but may be as high as 6 systems based on 3 known, large systems of fected by MTBE contamination, and discovery of potential future contamination events.

The exact cost for monitoring and treatment of MTBE for public water systems cannot be determined. It is estimated that if 390 small water systems located in rural areas have MTBE detections, then additional annual monitoring could be as high as \$217,000, assuming one contaminated water source per system. However, monitoring is likely to vary depending on the water system and MTBE concentrations and the necessity for installing treatment facilities or an alternate source cannot be predicted. It is estimated that a public water system that exceeds the MCL for MTBE, will have to conduct quarterly or more frequent monitoring for MTBE per affected entry point. The cost for analysis of MTBE is approximately \$140 per analysis. Therefore, the minimum additional cost for

MTBE analysis is \$560 per year. Treatment cost is dependent upon system size and number affected entry points and can be determined by the costs outlined in the table above.

Minimizing Adverse Impact

The adverse impact of this amendment is minimized since monitoring for MTBE will be included with the routine compliance monitoring for VOCs. Therefore, there will be no additional monitoring costs. The inclusion of MTBE will not modify the current monitoring criteria for a public water system. The MCL is a performance standard.

Rural Area Participation

Given the amount of local and national attention to MTBE issues, Public Outreach has occurred indirectly and independent of this proposed amendment and has affected all areas of the State, including rural areas. In addition, on November 9, 1999, Governor Pataki issued a press release announcing that the Department of Health would be initiating rule making to develop a stricter standard for MTBE. The general public, including the rural community, was given an opportunity to respond to the press release.

Job Impact Statement

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have a substantial adverse impact on jobs and employment opportunities.

Office of Mental Health

EMERGENCY RULE MAKING

Patients Committed to the Custody of the Commissioner

I.D. No. OMH-36-03-00001-E

Filing No. 918

Filing date: Aug. 20, 2003 Effective date: Aug. 20, 2003

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 540 of Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.09(b), (c) and 31.04(a); and Criminal Procedure Law, art. 730

Finding of necessity for emergency rule: Preservation of public safety. Specific reasons underlying the finding of necessity: This rule is necessary to streamline the currently lengthy and involved process of making determinations regarding fitness to stand trial and return to court of patients against whom criminal charges are pending.

Subject: Patients committed to the custody of the commissioner pursuant to Criminal Procedure Law, art. 730.

Purpose: To establish a faster and more appropriate process for determination of fitness to stand trial and return to court of a patient against whom criminal charges are pending.

Substance of emergency rule: Part 540 currently provides that the clinical director of a State operated forensics facility may apply to the court for the return of a patient in the custody of his or her facility where that patient's mental status has changed in terms of their capability of understanding the court proceedings and participating in their own defense. The current regulation involves a review by the hospital forensic committee in accordance with requirements of Section 510.09. This rule will streamline the process of making determinations regarding the fitness to stand trial and the return to court of the patients involved. It will establish that the clinical director is responsible for determining whether a patient remains an incapacitated person or is fit to stand trial. It outlines that the clinical director may designate certain facility psychiatrists to examine the patient and prepare a report and recommendation to the clinical director. While the clinical director will review and consider these recommendations, he or she need not follow them.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the State Register at some future date. The emergency rule will expire November 17, 2003.

Text of emergency rule and any required statements and analyses may be obtained from: Dan Odell, Bureau of Policy, Legislation and Regulation, Office of Mental Health, 44 Holland Ave., Albany, NY 12229, (518) 473-6945, e-mail: dodell@omh.state.ny.us

Regulatory Impact Statement

- 1. Statutory authority: Sections 7.09(b), 7.09(c) and Section 31.04(a) of the Mental Hygiene Law grant the Commissioner of the Office of Mental Health the authority and responsibility to adopt regulations that are necessary and proper to implement matters under his jurisdiction, the authority to administer the forensic psychiatric program, and the power to adopt regulations for quality control, respectively. Article 730 of the Criminal Procedure Law establishes the role of the Commissioner of Mental Health in the process of determining the fitness to stand trial.
- 2. Legislative objectives: Article 7 and Article 31 of the Mental Hygiene Law reflect the Commissioner's authority to establish regulations regarding mental health programs. Article 730 of the Criminal Procedure law reflects the role of the Commissioner of Mental Health in the process of determining the fitness to stand trial.
- 3. Needs and benefits: This amendment will streamline proper decision making regarding changes in custody status of patients who have been committed to the custody of an Office of Mental Health (OMH) forensic facility by a criminal court after having been found to have a mental illness which renders them incapable of understanding the court proceedings against them or participating in their own defense. OMH has a responsibility to take steps, in the interest of public safety, to see that these individuals are kept at the appropriate level of custody and are promptly returned to the court when their mental status changes.

Currently Part 540 provides that the clinical director may apply to the court for the return of a patient in the custody of his or her facility where that patient's mental status has changed in terms of their capability of understanding the court proceedings and participating in their own defense. The current regulation involves a review by the hospital forensic committee in accordance with requirements of Section 510.09. The hospital forensic committee reviews, due to difficulty of scheduling and additional paperwork, often consume a period of several weeks. This adds unnecessarily to the patient's length of stay and delays the defendant's ability to face a fair and speedy trial. It also results in overcrowding as patients who might otherwise return to court await the committee's action. This situation has become critical and immediate action is necessary to address it.

This rule will streamline the process of making determinations regarding the fitness to stand trial and the return to court of the patients involved. It will establish that the clinical director is responsible for determining whether a patient remains an incapacitated person or is fit to stand trial. It outlines that the clinical director may designate certain facility psychiatists to examine the patient and prepare a report and recommendation to the clinical director. While the clinical director will review and consider these recommendations, he or she need not follow them.

In summary, this amendment streamlines the process of determining fitness to stand trial. It supports sound decisionmaking and it maintains the final decisionmaking authority of the clinical director. This new process will meet all the requirements and expectations of the court orders involved.

4. Costs: It is estimated that this amendment could result in a savings of at least 2,000 hours of staff time per year at Mid-Hudson Forensic Psychiatric Center. It is also estimated that by streamlining this process there will be a reduction at that facility in patient length of stay, averaging between 14 to 21 days and resulting in a savings to the State of at least \$100,000 in associated costs.

There will also be significant savings to local governments. As required by subdivision (c) of Section 43.03 of the Mental Hygiene Law, the costs of care of patients receiving services while being held pursuant to order of a criminal court must be paid by the county in which such court located. OMH currently provides services to approximately 350 patients admitted under Article 730 of the Criminal Procedure Law. Counties are currently billed at a rate of \$301.00 per day of inpatient service. Based on an estimated 14 to 21 days reduction in length of stay the annual savings to counties, on a statewide basis, will be between \$1,475,000 to \$2,212,000.

- 5. Local government mandates: These regulatory amendments will not result in any additional imposition of duties or responsibilities upon county, city, town, village, school or fire districts. This regulation applies only to state-operated forensic facilities.
- 6. Paperwork: This rule should decrease and simplify the paperwork requirements.

RULE MAKING ACTIVITIES

Each rule making is identified by an I.D. No., which consists of 13 characters. For example, the I.D. No. AAM-01-96-00001-E indicates the following:

AAM - the abbreviation to identify the adopting agency

-the State Register issue number 01

96

00001 -the Department of State number, assigned upon receipt of notice

E -Emergency Rule Making-permanent action not intended (This character could also be: A for Adoption; P for Proposed Rule Making; RP for Revised Rule Making; EP for a combined Emergency and Proposed Rule Making: EA for an Emergency Rule Making that is permanent and does not expire 90 days after filing; or C for first Continuation.)

Italics contained in text denote new material, Brackets indicate material to be deleted.

Banking Department

EMERGENCY RULE MAKING

High Cost Home Loans

I.D. No. BNK-51-03-00009-E

Filing No. 1365

Filing date: Dec. 9, 2003

Effective date: Dec. 11, 2003

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 41 of Title 3 NYCRR. Statutory authority: Banking Law, sections 6-i and 6-1

Finding of necessity for emergency rule: Preservation of general wel-

Specific reasons underlying the finding of necessity: Chapter 626 of the Laws of 2002 is effective April 1, 2003. Provisions of chapter 626, by the enactment of section 6-1 of the Banking Law, will affect the making of certain home mortgage loans, known as high cost home loans, on after the effective date. Part 41 of Title 3 NYCRR has governed the making of such loans prior to the effective date and is not in conformity with certain provisions of the chapter 626. Also, in certain limited instances, the proposed amendments to Part 41 will clarify certain provisions enacted by chapter 626. Mortgage lenders and brokers and consumers should be aware of the revised regulatory requirements prior to the effective date of chapter

626 in order that mortgage loans made on and after April 1, 2003 conform legally to the statutory and regulatory requirements.

Subject: Making of certain residential mortgage loans, referred to as high cost home loans.

Purpose: To conform the provisions of Part 41 of Title 3 NYCRR to various provisions of section 6-1 of the Banking Law, and also clarify certain provisions of such section 6-1.

Substance of emergency rule: Section 41.1(a) is amended to revise the definition of a lender subject to part 41.

Section 41.1(b) is amended to revise the definition of an affiliate.

Section 41.1(c) is amended to make technical revisions.

Section 41.1(d) is amended to revise the definition of a bona fide loan discount point.

Section 41.1(e) is amended to revise the definition of a high cost home loan in regard to the points and fees threshold for determining such loans and limiting the exclusion of certain discount points in the computation of points and fees.

Section 41.1(f) is amended to revise the definition of loan amount.

Section 41.1(h) is amended to revise the definition of points and fees.

Section 41.1(j) is amended to make certain technical revisions.

Section 41.2(a) is amended to clarify the exceptions to the prohibition upon accelerating the indebtedness of high cost home loans.

Section 41.2(b) is amended to increase the term of a balloon mortgage to fifteen years.

Section 41.2(g), relating to modification and deferral fees, is repealed and then added as a new paragraph 2 to section 41.3(d), relating to refinancing of high cost home loans.

Section 41.3(a) is amended by adding a new disclosure requirement.

Section 41.3(b) is amended to revise requirements relating to the residual income guidelines and the presumption of affordability and to add certain conditions in order to determine that repayment ability has been "corroborated by independent verification."

Section 41.3(e) is amended to revise the percentage of points and fees that may be financed in making a high cost home loan, and to revise the charges that may be excluded from such financed points and fees.

Section 41.3(d) is re-titled and amended to revise the limitations upon points and fees that may be charged by particular lenders when refinancing high cost home loans and to add a previously repealed paragraph (see revisions to section 41.2(g)) relating to modification of an existing high cost home loan.

Section 41.3(f) is amended to delete a reference to median family

Section 41.3(g) is added to prohibit the refinancing of special mortgages, except under certain conditions.

Section 41.5(a) is amended to clarify deceptive acts relating to splitting or dividing loan transactions.

Section 41.5(b)(2) is amended to clarify retention of fees by lenders and brokers in relation to unfair, deceptive or unconscionable practices.

Section 41.5(b)(4) is amended to revise the definition of loan flipping, as an unfair or deceptive practice, and to add conditions to determine whether a loan has a net tangible benefit to the borrower.

Section 41.5(b)(6) is amended to clarify the standards to determine that recommending or encouraging default of a home loan or other debt is an unfair or deceptive practice.

Section 41.7 is amended to revise the legend that appears on a high cost home loan mortgage,

Section 41.8 is amended to delete VA and FHA mortgage loans from the definition of exempt products.

in the following table. This data represent gross amounts unless otherwise noted

Smoking Cessation Products	Fiscal Year 00-01*	Fiscal Year 01-02*
All Agents-Prescription and OTC	\$5,138,892	\$3,885,960
Prescription Agents	\$3,888,508	\$2,971,488
OTC Agents	\$1,250,384 \$312,596 (58 county share)	\$914,472

- Data Source DOH/OMM Audit, Fiseal & Program Planning Data Mart (5/15/2001)
- ** Data from 4/1/01 through 11/30/01

Fifty-eight (58) local social services districts administer the Medicaid Program in New York State and share in the cost of services provided to eligible recipients who receive Medicaid through their districts. For SFY 00-01, the local share for OTC smoking cessation products was \$312,596.

Compliance Requirements:

This amendment does not impose new reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Professional Services:

No new professional services are required as a result of this proposed action.

Compliance Costs:

There are no initial capital costs of compliance with this rule. The Department has provided data regarding the increase in gross pharmacy expenditures in the above table. The local government share of is also detailed in the above table.

Economie and Technological Feasibility:

The slight increase in Medicaid pharmacy costs associated with OTC smoking eessation products is offset by the long term savings in decreased hospital stays and other health care costs related to smoking and its secondary effects.

The proposed amendment will not change the way provider's bill for services or affect the way the local districts contribute their local share of Medicaid expenses for pharmacy. Therefore, there is no concern about the technological feasibility of this amendment.

Minimizing Adverse Economic Impact:

This regulation has no specific impact on small businesses other than to allow Medicaid reimbursement to pharmacies for OTC smoking cessation products. This should be seen by those pharmacies as a benefit. The slight increase in Medicaid costs to local governments as a result of the proposed rule should ultimately be offset by long term savings on health-care associated with smoking related illnesses in the Medicaid population. Both the Governor and the Commissioner have made public statements regarding their commitment to helping Medicaid eligible individuals to quit smoking.

Opportunity for Small Business and Local Government Participation:

The Department has discussed this proposed rule with representatives of the Pharmaeists Society of the State of New York and has presented it to the Department's Pharmacy Advisory Committee (composed of pharmaeists actively participating in the Medicaid program) and the Department's Medical Advisory Committee (composed of physicians actively participating in the Medicaid program). Information regarding the rule finalization was sent to all local districts and the Office of Medicaid Management did not receive any comments.

Rural Area Flexibility Analysis

No Rural Area Flexibility Analysis is required because the proposed rule, which merely adds over the counter smoking cessation products to the list of products covered by Medicaid, does not impose an adverse impact or rural areas and will not impose reporting, record keeping or other compliance requirements on public or private entities in rural areas. This finding is based on the fact that almost all of the products being added to the list of covered OTC products have previously been covered as prescription items.

Job Impact Statement

The Department has determined that this rule will not have a substantial adverse impact on jobs or employment opportunities. This rule makes available Medicaid reimbursement for over the counter smoking cessation products which were previously available by prescription only. No impact on employment is anticipated.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Public Water Systems-MTBE

I.D. No. HLT-36 -03-00009-A

Filing No. 1367

Filing date: Dec. 9, 2003 Effective date: Dec. 24, 2003

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Subpart 5-1 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 201(1) and 225(1)

Subject: Public water systems-MTBE

Purpose: To adopt a revised maximum containment level (MCL) of 0.010 mg/L for methyl-tertiary-butyl-ether (MTBE) and prescribe analytical procedures and monitoring requirements for affected public water systems.

Substance of final rule: Section 5-1.52, Table 3 is amended to add the following contaminant and to establish a more restrictive maximum contaminant level (MCL) of 0.010 MCL (mg/L for Methyl-tertiary-butyl-ether (MTBE).

Section 5-1.52, Table 9B is amended to add methyl-tertiary-butyl-ether (MTBE) as a contaminant for which monitoring would coincide with pre-existing principal organic contaminant monitoring requirements for community and nontransient noncommunity water systems.

Section 5-1.52, Table 13 is amended to extend the provisions for state, consumer or public notification to MTBE as required by this action.

Appendix 5-C, II. ORGANIC CHEMICALS, is amended to include a Section C. -Methyl-tertiary-butyl-ether (MTBE) Analytical Requirements. This section includes approved analytical methods, namely, EPA Method 502.2 (as most recently amended by the State) and EPA Method 524.2.

Section 5-1.22(b) is amended to reference the 1997 edition of the "Recommended Standards for Water Works" as this document is updated every five years, and currently, the 1987 edition is referenced. Section 5-1.22(b) is amended to also reference the 1995 edition of the Department's "Rural Water Supply" booklet, as the 1966 edition is currently referenced. The most current versions of these documents are already in widespread

Appendices 5-A and 5-B are amended to reflect the 1997 edition of the "Recommended Standards for Water Works" and the 1995 edition of "Rural Water Supply".

Final rule as compared with last published rule: Nonsubstantive changes were made in Appendix 5-C, subsection D.

Text of rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, fax: (518) 486-4834, e-mail: regsqna@health.state.ny.us

Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Although the regulation has been changed since it was published in the State Register on September 10, 2003, the changes do not necessitate any changes to the Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis, or Job Impact Statement.

Assessment of Public Comment

In total, 3 comments were received regarding the proposed rule making: 2 private individuals and 1 environmental activist group responded. All comments are in accord with the proposed rule, establishing a maximum contaminant level (MCL) of 0.010 milligrams per liter for MTBE in public drinking water systems. One response included a comment that they did NOT support any of the alternatives listed in the proposal, which included: to keep the existing MCL of 50 parts per billion; or to wait for the federal government to establish an MCL for MTBE.

It should be noted that a typographical error was identified in the proposed rule making notice. In the section entitled "Substance of proposed rule", the MCL is incorrectly reported as 0.10 mg/L, instead of 0.01 mg/L. This typographical error does not occur in any other location of the notice and does not affect the text of the regulation.